REMARKS

Claim amendments

Claims 1, 10 and 12-15 have been amended to replace "medicament" with "immunogenic composition." Support for the amendment can be found, for example, in paragraphs 0015 and 0016, and in paragraph 0081, of U.S. Patent Application Publication No. US 2004/0142002, which is the publication of the instant application.

Claim 1 has been amended further to delete the phrase "for use in treatment or prophylaxis."

Claims 13 and 14 have been amended to replace "nucleotide sequences" with "a nucleotide sequence." Support for the amendment can be found, for example, in paragraph 0050 of U.S. Patent Application Publication No. US 2004/0142002.

Rejection of Claims 1, 10 and 12-15 under 35 U.S.C. §112, first paragraph

Claims 1, 10 and 12-15 are rejected under 35 U.S.C. §112, first paragraph because the "specification does not provide an adequate enablement for the claimed medicament" (Office Action, page 4). Specifically, the Examiner stated that "[w]hile the claims are enabled for inducing an immunogenic response, the claims do not recite immunogenic compositions" (Office Action, page 3).

To clarify the claimed subject matter, Applicants have amended Claims 1, 10 and 12-15 to be directed to an immunogenic composition comprising a recombinant poxvirus which is genetically engineered to be incapable of expressing a native A41L protein, together with a pharmaceutical acceptable carrier.

In the specification as filed, Applicants demonstrate that, by deleting the A41L gene, a poxvirus of the claimed invention becomes more immunogenic. Specifically, using a rabbit model, Applicants demonstrate that injecting a rabbit subcutaneously with a recombinant A41L deletion mutant vaccinia virus (vΔA41L) causes greater infiltration of the surrounding tissue by leukocytes, implying that the deletion makes the virus more visible to the immune system. Applicants teach that "[i]mmunostaining of lesions infected with vΔA41L using anti-rabbit CD43 antibody, revealed intense infiltration of CD43+ cells (stained reddish brown), in the lower vascular regions of the skin, as compared to that of vA41L and vA41L-rev, which

exhibited few infiltrating cells" (US 2004/0142002, paragraph 0081). Applicants further teach that "the A41L protein could down-modulate the infiltration of monocytes, macrophages and Tlymphocytes [sic] during an anti-viral immune response in vivo" and that "[t]his contrasts with the vΔA41L virus, which displayed reduced viral spread when confronted with immune infiltration" (US 2004/0142002, paragraph 0081). These teachings clearly indicate that vΔA41L causes an immune response in a rabbit model *in vivo*, as evidenced by infiltration of leukocytes, namely monocytes, macrophages and T lymphocytes, into tissues surrounding virally-induced lesions.

Thus, Applicants have provided an enabling disclosure for the full scope of the claimed invention, particularly as amended.

Rejection of Claim 14 under 35 U.S.C. §112, second paragraph

Claim 14 is rejected under 35 U.S.C. §112, second paragraph "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention" (Office Action, page 4). Specifically, the Examiner stated that there is insufficient antecedent basis in the specification for "wherein the nucleotide sequences are set forth in SEQ ID NO: 1." (Office Action, page 4).

Applicants have amended Claim 13 to replace "nucleotide sequences encoding the native A41L protein" with "a nucleotide sequence encoding the native A41L protein," and amended Claim 14 to replace "wherein the nucleotide sequences are set forth in SEQ ID NO: 1" with "wherein the nucleotide sequence is set forth in SEQ ID NO: 1," thereby obviating the rejection.

Rejection of Claims 1 and 7-11 on the ground of nonstatutory obviousness-type double patenting

Claims 1 and 7-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,355,252.

To obviate the double patenting rejection, Applicants are filing concurrently with this Amendment a terminal disclaimer in compliance with 37 C.F.R. §1.321(c), signed by Applicants' Agent. The fee for filing a statutory disclaimer in the amount of $130.00, pursuant to 37 C.F.R. § 1.20(d), is also enclosed.

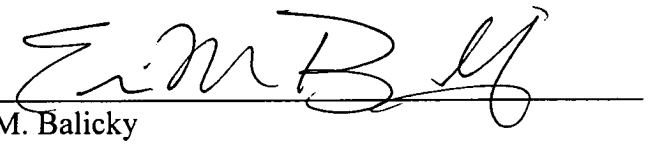
In light of the terminal disclaimer, the rejection should be withdrawn.

CONCLUSION

In view of the above amendments, remarks and terminal disclaimer, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

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Date: December 21, 2007